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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,732	06/12/2001	Gary Bee	089498-0402	4949

20583 7590 06/03/2005

JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/880,732

Applicant(s)

BEE ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 59-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 59-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **FINAL ACTION**

1. This action is in response to the Amendment filed April 19, 2004, the Response and Amendment including new drawings filed October 25, 2004, and the Sequence Listing filed March 2, 2005. It is noted that the drawings filed October 25, 2004 have now been accepted, and that the Sequence Listing filed March 2, 2005 has been entered.
2. Claims 72-74 have been canceled, and claims 1, 4-5, 9, 59, and 62-71 have been amended. Claims 1-6, 9, and 59-71 are now pending and under consideration. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

4. Claim 66 is objected to because of the following informalities: the claim recites the phrase "said nucleic acid molecule that comprises said target nucleotide sequence are fragmented" rather than, e.g., phrase "said nucleic acid molecule that comprises said target nucleotide sequence is fragmented". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. It is noted that, in view of the cancellation of claims 72-74, the rejections of those claims under 35 USC 112, second paragraph set forth in the prior Office action are moot.

6. Claims 1-6, 9, and 59-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 9, and 59-71 are indefinite over the recitation of the term “non-evanescent wave light” in claim 1, for reasons set forth in the Office action of December 18, 2003. The response traverses the rejection on the grounds that “the usage of the term in the claim is unambiguous and consistent with the art-known meaning.” The response briefly describes how evanescent wave light may be generated, states that “Arrangements of light source and sample to achieve or avoid evanescent light illumination are well known to those skilled in the art,” and cites as an example US Patent No. 5,843,651, which “provides a detailed description of evanescent wave illumination.” These arguments have been thoroughly considered but are not persuasive. The claims were rejected due to the recitation of the term “non-evanescent wave light” (not the term “evanescent wave light”). As stated in the prior action:

....it is well-known to those of skill in the art that light of various types and from various sources may be used in such a manner so as to produce an evanescent wave or field, or, alternatively, be used in such a manner so as not to produce such an evanescent wave or field. Accordingly, it is unclear as to what would constitute “non-evanescent wave light” within the context of the claims, and as to what types of light sources or method steps are excluded by this claim language. Particularly, it is unclear as to whether the claims are intended to be

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limited to the use of a particular type of light source, whether the claims are intended to exclude method steps in which light is used in such a way so as to produce an evanescent wave or field, in which the use of an evanescent wave or field as a beam in light scattering is excluded, etc.

Thus, the issue is whether one of skill in the art, when reading applicants' claim, would understand what is excluded by applicants' use of the term "non-evanescent wave light." While the response argues that this terminology is well known, applicants' response addresses the meaning of "evanescent wave light," rather than the meaning of "non-evanescent wave light." In a further attempt to determine whether this terminology is in fact well-known, the examiner conducted a separate, further search of several databases for this term. However, 0 hits were obtained in an STN search of several databases (Biosis, Biotechno, Caplus, Embase, Lifesci, Medline, and Scisearch), and a WEST search of the USPT, PGPB, and DWPI databases resulted in only 3 hits, one of which was the instant application, with the other 2 hits appearing in patents of which 2 inventors of the instant invention are co-inventors. Thus, applicants' argument that this terminology is well-known is not persuasive. Clarification with regard to how the term "non-evanescent wave light" is limiting with respect to the instant claims is still required, and therefore this rejection is maintained.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:

Claims 1-6, 9, and 59-71 are indefinite over the recitation of the phrase "detecting light scattered by said one or more scattered-light detectable particles under said conditions which indicates the presence of said allele in said sample."

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The language "which indicates....sample" appears to modify the term "conditions" in this phrase, such that it is not clear what would be considered indicative of the presence of "said allele." This rejection could be overcome by amending the claim to recite, e.g., "...under said conditions as indicative of the presence of said allele."

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

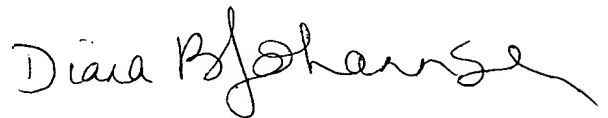
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen  
Primary Examiner  
Art Unit 1634  
May 31, 2005